WSIRB Review Worksheet

Reviewer:_____ **Review Date:**_____

Project Title:_____ **Project#:**_____ **Investigator:**_____

	Yes	No	Review Comments
PURPOSE OF THE STUDY/SCIENTIFIC MERIT:			
Are the purposes, objectives, and hypotheses of the research clear?	☐	☐	
Is adequate background, rationale, and relevance for the project provided? (Including literature review.)	☐	☐	
Is the methodology appropriate in light of the stated purposes, objectives, and hypotheses?	☐	☐	
Is the sample size adequate for the proposed study design?	☐	☐	
Is it clear how the study data will be analyzed?	☐	☐	
Will the analysis produce results that are logically related to study purposes, objectives and hypotheses?	☐	☐	
Considering the complexity of the project, does it appear that the investigator is qualified to conduct this research independently?	☐	☐	
If no, are there provisions for appropriate consultation or supervision?	☐	☐	
Does the investigator have a potential conflict of interest?	☐	☐	
STUDY POPULATION:			
Is it clear who will be enrolled as research subjects or whose records will be used in the research?	☐	☐	
Is the subject selection appropriate for the study objectives?	☐	☐	

	Yes	No	Review Comments
Is adequate justification provided for subject inclusion/exclusion criteria? (e.g. gender, race-ethnicity, age, language, clinical status)	☐	☐	
Does the study involve vulnerable groups? (pregnant women, fetuses, children, decisionally impaired, prisoners, institutionalized, socially or economically disadvantaged)	☐	☐	
If children and/or prisoners are included, please complete additional checklists.			
SUBJECT RECRUITMENT			
Does the researcher request access to individually-identifiable records for sampling participants?	☐	☐	
Is the researcher requesting access to records without prior consent? (If yes, please refer to consent waiver matrix on page 6.)	☐	☐	
Is the first contact with potential subjects made by an appropriate individual or agency? (The researcher generally should **not** make first contact with potential subjects.)	☐	☐	
Is the setting for recruitment (location and timing) appropriate?	☐	☐	
Were all recruitment materials submitted? (posters/flyers; brochures; contact letters; telephone scripts; TV, radio, newspaper ads; press releases; internet postings)	☐	☐	
Are the recruitment materials acceptable as submitted? (Please mark all corrections, additions and comments on recruitment materials and turn them in with this worksheet.)	☐	☐	
INFORMED CONSENT:			
Does the researcher request to **alter** or **waive some or all** of the informed consent requirements, per 45 CFR 46.116? If yes, please refer to the waiver of consent matrix on page 6.	☐	☐	

	Yes	No	Review Comments
Does the researcher request a waiver of documentation of signed consent? If yes, please refer to the waiver of consent matrix on page 6.	☐	☐	
Does the researcher request a waiver of parental consent? If yes, please refer to waiver of consent matrix on page 6.	☐	☐	
Is the setting (location and timing) for the consent process appropriate?	☐	☐	
Should there be a subject advocate or consent witness to ensure that subjects understand research participation and make decisions voluntarily?	☐	☐	
Does the research involve subjects who may have diminished capacity?	☐	☐	
If yes, does the researcher explain how he/she will assess whether subjects have sufficient capacity to provide informed consent?	☐	☐	
If a potential subject is not capable of providing informed consent, will proxy consent be sought from a legal guardian?	☐	☐	
Does the research involve subjects living in an institutional setting that could involve coercive elements?	☐	☐	
If so, are there adequate measures to ensure that decisions regarding research participation are voluntary?	☐	☐	
Is an assent form needed? (ages 12-17)	☐	☐	
Is an assent statement/oral consent needed? (ages 7-11)	☐	☐	
<u>Consent documents</u> Were ***all*** consent documents, assent forms, consent scripts submitted? If not, what is missing?	☐	☐	
Do the consent form(s)/script(s) contain the following elements:			
• Investigator's name, affiliation, address, and telephone number.	☐	☐	
• A clear statement that the project involves research.	☐	☐	

	Yes	No	Review Comments
• An adequate explanation of the purpose of the research.	☐	☐	
• A description of any benefits to individual subjects or others which may be reasonably expected from the research.	☐	☐	
• A description of the study population and number of participants.	☐	☐	
• A description of how and why subjects were sampled for participation.	☐	☐	
• A description of all research procedures.	☐	☐	
• A description of the time frame and sequence of activities involved with research participation.	☐	☐	
• A description of any alternative procedures or treatments.	☐	☐	
• A description of any reasonably foreseeable risks, stresses or discomforts.	☐	☐	
• A description of procedures and safeguards to minimize risks.	☐	☐	
• An explanation of the use of any individually-identifiable records.	☐	☐	
• An explanation of who will have access to identified research records.	☐	☐	
• A description of methods to protect confidentiality of research records and timeline for destruction of research records.	☐	☐	
• Examples of the most sensitive questions on study instruments.	☐	☐	
• An explanation of compensation for research participation, if any.	☐	☐	
• statement indicating that participation is voluntary and there is no penalty or loss of benefits for skipping questions, not participating, or withdrawing from the study.	☐	☐	
• Name and phone number for person(s) to contact regarding questions about the study.	☐	☐	
• Name and phone number for person(s) to contact regarding questions about the rights of research subjects.	☐	☐	
• Appropriate reading level and font size for the intended study population.	☐	☐	
• List of parties who will receive the consent form.	☐	☐	
• Translation into appropriate language(s).	☐	☐	

(Please mark corrections, additions and comments on ***each*** consent document and turn them in with this worksheet.)

	Yes	No	Review Comments
STUDY INSTRUMENTS:			
Were all study instruments including questionnaires, assessments, interview scripts submitted?	☐	☐	
Are the study instruments appropriate for the purposes of the research?	☐	☐	
Do the study instruments have demonstrated validity and reliability?	☐	☐	
If not, have they been pilot tested?	☐	☐	
OTHER:			
Are there adequate provisions and safeguards to protect the privacy of participants and the confidentiality of research records?	☐	☐	
Does the investigator plan to obtain a Certificate of Confidentiality?	☐	☐	
Are subjects provided compensation for research participation?	☐	☐	
If yes, is the compensation appropriate for the procedures and time involved?	☐	☐	
Is the application complete and are forms signed as required?	☐	☐	
If not, please indicate what is missing.			

Waiver of Consent Matrix

☐ **No waiver or alteration of consent requirements is requested.**

Indicate TYPE of waiver(s) or alteration(s) requested: ***Indicate PURPOSE of waiver or alteration:***

	Waiver or alteration of consent requirements may be approved provided the following conditions are met, per 45 CFR 46.116.	☐ **Contact Information**		☐ **Record Review**		☐ **Study Participation**	
		Yes	**No**	**Yes**	**No**		
☐	**Waiver of informed consent:** • The research could not be practicably carried out without the waiver; • The research involves no more than minimal risk; • The waiver will not adversely affect the rights and welfare of the subjects; • Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐		
☐	**Alteration of some elements of consent requirements:** • The research could not be practicably carried out without the waiver; • The research involves no more than minimal risk; • The waiver will not adversely affect the rights and welfare of the subjects; • Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	**Yes** ☐ ☐ ☐ ☐	**No** ☐ ☐ ☐ ☐
☐	**Waiver of documentation of signed informed consent:** • The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. or • The research involves no more than minimal risk, and involves no procedures, for which written consent is normally required outside of the research context.	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
☐	**Waiver of parental consent:** • Parental or guardian permission is not a reasonable requirement to protect subjects. • An appropriate mechanism is provided to protect subjects.	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐

	Yes	No	Review Comments
RISK/BENEFIT ANALYSIS:			
Risks			
Are there physical or medical risks related to study participation? Not more than minimal risk? ☐ Greater than minimal risk? ☐	☐	☐	
Are there psychological or emotional risks related to study participation? Not more than minimal risk? ☐ Greater than minimal risk? ☐	☐	☐	
Are there social, economic, or legal risks related to study participation? Not more than minimal risk? ☐ Greater than minimal risk? ☐	☐	☐	
Are there other risks related to study participation? Not more than minimal risk? ☐ Greater than minimal risk? ☐	☐	☐	
Are there adequate safeguards to reduce risks and protect the rights and welfare of participants? If not, what additional safeguards should be implemented?	☐	☐	
Benefits			
Are there direct benefits to individual research participants?	☐	☐	
Are there benefits to the class of subjects recruited for research?	☐	☐	
Is there potential for gain in practical knowledge relevant to solution of societal problem?	☐	☐	
Is there potential for gain in basic scientific knowledge?	☐	☐	
Does the project provide professional training for a student?	☐	☐	
Analysis			
Are the **risks** to subjects **reasonable in relation to the anticipated benefits** to the subjects and/or society?	☐	☐	
If not, are there ways to increase benefits and/or reduce risks to improve the risk/benefit ratio?	☐	☐	

	Yes	No	Review Comments
DISPOSITION RECOMMENDATION:			
Approve the project as submitted?	☐	☐	
Approve project conditionally? List approval conditions:	☐	☐	
Hold project in abeyance? List issues:	☐	☐	
Disapprove project?	☐	☐	